

The Essentials of Clinical Research at Stanford (EPI- 273)
Winter Quarter 2026
Thursdays from 4:00 – 6:00 p.m., January 8 to March 12
Virtual | Register Here

Course Director	Spectrum Staff
Steve Goodman, MD, MHS, PhD Professor (Epidemiology and Population Health) Associate Dean of Clinical and Translational Research	Emily Maxwell Coordinator, Workforce Development Peg Tsao, RN, CCRC Associate Director, Clinical Research Operations

The Essentials of Clinical Research course is designed for faculty, trainees and staff engaged in clinical research at Stanford and consists of 10 sessions. The course introduces attendees to basic principles of clinical research design, including biostatistics; design and interpretation of diagnostic and predictive test studies; required and desired elements of clinical trial protocols. The course will also introduce regulatory aspects of clinical research conduct and oversight, Good Clinical Practice (GCP), and ethical dimensions of clinical research.

A Certificate of Participation will be presented to those who attend a minimum of 8 sessions, complete the associated session quizzes and evaluations, and submit a final course assessment.

The Course will also offer a maximum of 20 Continuing Medical Education (CME) units and or 20 Board of Registered Nursing (BRN) contact hours.

Text: Highly recommended

Designing Clinical Research: An Epidemiologic Approach, 4th Edition (available as e-text via Lane Library)
 Stephen B. Hulley (editor), Steven R. Cummings, Warren S. Browner, Deborah Grady, Norman Hearst, Thomas B. Newman. Publisher: Lipincott Williams and Wilkins

Other Resources:

PCORI Methodology Report

(<https://www.pcori.org/research/about-our-research/research-methodology/pcori-methodology-report>)

ICH guidelines (<http://www.ich.org/products/guidelines.html>)

GCP guidelines

(https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf)

SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) (<http://www.spirit-statement.org/>)

Enhancing the QUALity and Transparency Of health Research [EQUATOR]

(<http://www.equator-network.org/reporting-guidelines/>)

Other recommended textbooks:

Fundamentals of Clinical Trials (available as e-text via [Lane Library](#))

Lawrence M. Friedman, Curt D. Furberg, David L. DeMets

Course outline: The Essentials of Clinical Research at Stanford (EPI 273)			
Day	Date	Topic	Instructor
Thurs	1/8	Session 1: Getting Started: The Research Landscape (Overview) Research Question Design Measurements Analysis/Interpretation/Reporting	Steven Goodman
Thurs	1/15	Session 2: Foundations of Statistics P-values, confidence interval, hypothesis testing, sample size.	Steven Goodman
Thurs	1/22	Session 3: Designing and Conducting RCTs - Early Phase trials - Phase 2 and 3 trials Randomization Outcomes Analytic Approach - Risks, Rates, Kaplan-Meier - Measures of Association in RCTs: RR, AR, difference in means, NNT	Rita Popat
Thur	1/29	Session 4: Qualitative Research and Questionnaire Design - Collect, analyze, integrate o Quantitative research (e.g., experiments, surveys) o Qualitative (e.g., focus groups, interviews)	Bonnie Halpern-Felsher
Thurs	2/5	Session 5: Designing and Conducting Observational Studies - Cohort - Case-control - Cross-sectional Sources of bias Analytic Approach - Measures of Association (RR, OR) - Overview of regression models	Rita Popat
Thurs	2/12	Session 6: Research Reproducibility, Data Management and Collection - Statistical analysis tool - Data Science - Reporting	Steven Goodman John Borghi Haley Hedlin
Thurs	2/19	Session 7: Ethics and Diversity in Clinical Research - Responsible Conduct of Research- What is misconduct? - Rules of Science	Holly Tabor Lisa Goldman Rosas

Thurs	2/26	Session 8: Developing a Clinical Protocol <ul style="list-style-type: none"> - Scientific Merit - IND/IDE Requirements - Clinical Research Objectives - Clinical Study Design - Data Safety Monitoring Boards (DSMB) - Clinical Trials.gov Registration 	Mark Pegram Scott Patton
Thurs	3/5	Session 9: Implementing a Clinical Protocol <ul style="list-style-type: none"> - Study Startup <ul style="list-style-type: none"> o Regulatory Review o Budgeting and Contracts o Study team training - Study Conduct <ul style="list-style-type: none"> o Good Clinical Practice o Delegation of Authority o The Informed Consent Process o Essential Records and Documentation 	Peg Tsao
Thurs	3/12	Session 10: Study Closeout, Publications and What's Next? <ul style="list-style-type: none"> - Statistical Analyses <ul style="list-style-type: none"> o Statistical Analysis o Independent Validation - Trial Committees, Presentations, Publications - Data Sharing/ Open Source 	Mario Malicki Peg Tsao Scott Patton Haley Hedlin Meghan Halley Rita Popat
	VIDEO	BONUS: Design and Analysis of Tools for Diagnosis & Prediction <ul style="list-style-type: none"> - How to structure a diagnostic test evaluation question - Phases of diagnostic test evaluation - The mathematics of evaluating diagnostic tests 	Steven Goodman

Students with documented disabilities: Students who may need an academic accommodation based on the impact of a disability must initiate the request with the Student Disability Resource Center (SDRC) located within the Office of Accessible Education (OAE). SDRC staff will evaluate the request with required documentation, recommend reasonable accommodations, and prepare an *Accommodation Letter* for faculty dated in the current quarter in which the request is being made. Students should contact the SDRC as soon as possible since timely notice is needed to coordinate accommodations. The OAE is located at 563 Salvatierra Walk (phone: 723-1066).